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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/664,225

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EXAMINER

ALEXANDER, LYLE

ART UNIT

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1797

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/664,225	Applicant(s) VON BAHR ET AL.	
	Examiner LYLE A. ALEXANDER	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-13, 19-23, 26, 27 and 29-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-13, 19-23, 26, 27 and 29-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/15/09</u> . | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9,11-13, 29-30,32-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is not clear where the flow regulator is placed relative to the inlet, NO scrubber and buffer. How can both the presently claimed “- an inlet/outlet ...” both be configured to provide “NO-scrubbed” are to the patient ? Claim 1 is further confusing because it is not clear lines 5-6 provide any new structure that is not claimed in lines 3-4. Clarification could be achieved by claiming the physical positions of each of the claimed elements, such as “a NO scrubber having an inlet and an outlet where air NO-scrubbed air is supplied to the patient through the outlet...”. Finally, claim 1 is not clear how the flow regulator can be positioned between the inlet/outlet and the buffer chamber. Presumably the flow regulator is positioned between the outlet of the buffer chamber and the inlet of the electrochemical sensor. As the invention is best understood, there is a device attached to the NO scrubber where the patient inhales and a second inlet where the patient exhales the NO scrubbed air. Clarification is requested.

Claim 6 is confusing because claim 1 does not claim separate devices for inhalation and exhalation.

Claim 15 is not clear what intended by "adapting to different users."

Claim 19 is not clear how if the air inhaled by the patient has been through any one of or all of the "electrochemical NO sensor", the "NO scrubber" and the "buffer chamber". Additionally, the claim is not clear what "flow rate" is intended by the claimed "suitable" flow rate.

Claims 32-34 are not clear to the physical position of each element.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,4-9,12-13, 19-22, 26-27, 29, 30-35 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Mault et al. (USP 6,468,222).

Mault et al. teach a metabolic calorimeter that measures respirator gases, such as nitric oxide. Columns 1-2 lines 65-teach a flow meter that generates electrical signals as a function of the flow volumes of inhaled and exhaled gases. These signals are transferred to a computation unit to assist in the various calculations. This has been read on the claimed "electronics for verifying the parameters of the inhalation and controlling the parameter of the exhalation." Column 8 lines 28+ teach a temperature sensor(90), ambient pressure sensor(92), and a relative humidity sensor(94). Column 9 lines 44+ teach the ambient temperature, relative humidity, pressure, inhalation/exhalation volumes and gas concentration are all measured. Column 29 line 52 teaches the use of an electrochemical sensor. Column 30 lines 48-63 teach the use of a scrubber to remove the analyte of interest from the gas being inhaled by the patient

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prior to exhalation(filter module(322) in figure 21). Column 31 lines 49-53 teach the analyte of interest can be nitric oxide. Column 32 lines 18-39 teach the device communicates with the users with data analysis, display and other types of feedback. This has been read on the claimed "audible or visual feedback."

Additionally, in light of the 9/15/09 amendments and remarks, the Office has reconsidered the interpretation of the claimed "buffer chamber" in light of page 11 lines 11-18 that teach the "... said buffer chamber is formed as a long channel with a small cross-section " or "... said buffer chamber is formed as a length of tubing ... ". The Office has read the claimed "buffer chamber" in light of the specification on the flow tube(36) taught by Mault et al.

The new limitations directed to "a flow regulator positioned between the inlet/outlet and the buffer chamber" has been read on the concentric chamber(48) taught by Mault et al.

New claim 35 requires means to supply the sample from the NO scrubber to the electrochemical sensor. Mault et al. teach in column 30 lines 48-63 a scrubber(e.g. filter module(322)) to remove the analyte of interest from the gas being inhaled by the patient prior to exhalation into the electrochemical sensor(84). The sample enters the device(10) through grill(72), contacts the patient through the taught network of conduits and is expelled through the same network to sensor(84) which has been read on claim 35.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 2-3,23 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mault et al.

See Mault et al. supra.

Mault et al. are silent to the claimed air flow rates.

The court decided In re Boesch (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable is one that has well known and predictable results. The selection of the rate of a fluid flow through a device is a result effective variable that is dependent upon the volumes of the sample required, the size of the device and the type of sensors. It would have been within the skill of the art to modify Mault et al. and construct the device to have an exhalation air flow of 20-800 ml/s into the buffer chamber, a flow rate of 0.5-15 ml/s to the sensor and a flow rate of 45-55 ml/s to the buffer chamber as optimization of a result effective variable.

Claims 14-15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mault et al. in view of Holowko et al.

See Mault et al. supra.

See the appropriate paragraph of the previous Office action for the teachings of Holowko et al.

Mault et al. are silent to the claimed "smart card."

Holowko et al. teach a medical device that uses "smart card" to ensure only the authorized individuals can use the device or access the data. The smart card is further desirable because the patient does not have to re-enter their information each time which will minimize input errors.

It would have been within the skill of the art to further modify Mault et al. in view of Holowko et al. and use a "smart card" to gain the above advantage.

Claims 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mault et al. in view of Birks et al.

See Mault et al. supra.

See the appropriate paragraph of the previous Office action for the teachings of Birks et al.

Mault et al. are silent to the use of a piston to compress or control the volume and pressure of the device.

Birks et al. teach a device that employs a piston to control the volume and pressure in the device. Control of the volume and pressure is desirable because this will optimize the performance of the device and sensor. It would have been within the skill of the art to further modify Mault et al. in view of Birks et al. and use a piston to compress or control the volume and pressure of the device to gain the above advantages.

Response to Arguments

Applicant's arguments filed 9/15/09 have been fully considered but they are not persuasive.

Applicants' traverse the 35 USC 112 second paragraph rejections and state the 9/15/09 amendments have clarified all of these issues. The Office does not agree and directs Applicants' to the above 35 USC 112 second paragraph rejections.

Applicants' remarks concerning the 35 USC 112 second paragraph rejections claims 29 and 31 were convincing.

Applicants' state Mault et al. fail to teach the claimed "buffer chamber", the claimed "electrochemical NO sensor and means to supply the sample to the electrochemical sensor. The Office has reconsidered the claimed "buffer chamber" in light of the original disclosure, such as that on page 11 lines 11-18, and concluded this limitation is fully met by flow tube(36) taught by Mault et al.

Applicants' state Mault et al. teaches an electrochemical oxygen sensor and not the claimed NO sensor. These remarks are not convincing because Mault et al. teach in column 3, as acknowledged by Applicants", measurement of NO which teaches the taught electrochemical sensor is both capable of measuring NO and also used to measure NO. The electrochemical sensor taught by Mault et al. is capable of measuring NO, is taught as used for measuring NO and has been properly read on the claimed electrochemical NO sensor.

Mault et al. teach in column 30 lines 48-63 a scrubber(e.g. filter module(322)) to remove the analyte of interest from the gas being inhaled by the patient prior to exhalation into the electrochemical sensor(84). The sample enters the device(10)

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through grill(72), contacts the patient thought the taught network of conduits and is expelled through the same network to sensor(84) which has been read on the claimed means to supply the sample to the electrochemical cell.

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYLE A. ALEXANDER whose telephone number is (571)272-1254. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is

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available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lyle A Alexander/

Primary Examiner, Art Unit 1797